

Applicants: Maureen J. Charron and Ellen B. Katz
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REMARKS

Claims 1-20 are pending in the subject application. By this Amendment, applicants have amended claims 1 and 11. Accordingly, upon entry of this Amendment, claims 1-20 as amended will be pending and under examination.

Applicants maintain that the amendments to claims 1 and 11 do not raise an issue of new matter. Support for the amendments to claims 1 and 11 can be found *inter alia* in the specification on page 6, line 35, through page 7, line 30, and in claims 4, 8, 14, and 18.

Accordingly, applicants respectfully request that the Amendment be entered.

Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1, 4-10, 11 and 14-20 are rejected under 35 U.S.C. §112, second paragraph, as indefinite because the recitation of "defect in cell proliferation" does not clearly define what is included and excluded as a defect in cell proliferation.

Independent claims 1 and 11 have hereinabove been amended to recite that "the defect in cell proliferation is a hyperplasia, a pre-neoplastic lesion or a neoplasm..." Hyperplasias, pre-neoplastic lesions and neoplasms are described in the specification at least on page 6, line 35, through page 7, line 30.

Accordingly, in view of the amendments and remarks made hereinabove, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Claims 1-5 and 11-14 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting a step for detecting GLUTx expression.

Independent claims 1 and 11 have hereinabove been amended to recite that "the diagnostic sample is assayed using an agent reactive with GLUTx protein or using at least one nucleic acid probe which hybridizes to nucleic acid encoding GLUTx protein..."

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Agents that react with GLUTx protein and nucleic acid probes that hybridize to nucleic acid encoding GLUTx protein are described in the specification at least on page 10, line 5, through page 13, line 18.

Accordingly, in view of the amendments and remarks made hereinabove, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-20 are rejected under the written description requirement of 35 U.S.C. §112, first paragraph. The Examiner stated that only a method for determining whether a subject has endometrial cancer comprising assaying for GLUTx expression, but not for the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicants respectfully traverse this rejection.

As noted above, hyperplasias, pre-neoplastic lesions and neoplasms are described in the specification at least on page 6, line 35, through page 7, line 30.

Furthermore, in addition to endometrial cancers, working examples are provided in the specification for metastasizing (MTLn3) and non-metastasizing (MTC) (rodent) adenocarcinoma breast cancer cells (page 38, line 15, through page 39, line 2; page 42, lines 5-25; page 3, line 34 through page 4, line 21; Figures 2-4) and mouse mammary tumors that were generated by over expression of oncogenes (page 41, lines 26-36; page 3, lines 27-33; Figure 1).

Applicants note that “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention” (MPEP §2163) and that “[t]he written description requirement for a claimed

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genus may be satisfied through sufficient description of a representative number of species.” (MPEP §2163.05)

Accordingly, in view of the amendments and remarks made hereinabove, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Rejections under 35 U.S.C. §102(e)

Claims 1-20 are rejected under 35 U.S.C. §102(e) as anticipated by Baughn et al. (U.S. Patent Application Publication No. US 2003/0171275 A1, December 20, 2000).

Applicants respectfully traverse this rejection.

Applicants note that:

A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir.1990). In addition, the reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Id. In re Paulsen*, 30 F.3d 1475, 1478-1479, 31 USPQ 2d 1671, 1673 (Fed. Cir.1994).

Baughn et al. do not disclose that expression of a polypeptide having the sequence set forth in SEQ ID NO:1 is elevated above normal when a subject has a hyperplasia, a pre-neoplastic lesion or a neoplasm, as required by the inventions claimed in claims 1 and 11.

Furthermore, Baughn et al. do not enable the present invention. Baughn et al. do list disorders that are associated with expression of human transporters and ion channels (TRICH). Examples of over 230 such specific disorders are listed in paragraph [0252] spanning pages 26-27. Baughn et al. also list disorders that are associated with decreased expression or activity of human transporters and ion channels (TRICH). Examples of these disorders are listed in paragraph [0199] spanning pages 20-21. Note that the same list of over 230 specific disorder is presented as being associated both with

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expression of TRICH and with decreased expression of TRICH. Baughn et al. list 27 polypeptide sequences (TRICH) in Tables 1-3 (see also paragraphs [0150]-[0153] on page 14). Thus, at best, Baughn et al. present an invitation to experiment to determine which TRICH is under expressed or over expressed in association with which disorder. There are at least 12,420 possible combinations to be tested in Baughn et al. (230 disorders X 27 peptides X 2 expression states (over or under expressed) = 12,420).

Accordingly, applicants maintain that Baughn et al. do not anticipate the claimed invention and respectfully request reconsideration and withdrawal of this ground of rejection.

CONCLUSIONS

In view of the amendments and remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in the December 30, 2003 Office Action and earnestly solicit allowance of the claims under examination, namely claims 1-20.

No fee is deemed necessary in connection with the filing of this response. However, if any fee is required to preserve the pending of the subject application, authorization is hereby given to charge any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

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